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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,711	01/27/2004	W. James Jackson	2479.0040003/BJH/C-K	4900

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,711	JACKSON ET AL.	
	Examiner	Art Unit	
	PADMA v. BASKAR	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-132* is/are pending in the application.

4a) Of the above claim(s) *87-90,93-96,112-115 and 118-121* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-86,91,92,97-111,116,117 and 122-132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/23/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on 2/11/08 is acknowledged and has been entered.

Status of Claims

2. Claims 1-82 have been canceled.

New claims 83-132 have been added.

Claims 83-86, 91-92, 97-111, 116-117 and 122-132 are under examination with respect to elected SEQ.ID.NO:2.

Claims 87-90, 93-96, 112-115, 118-121 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention (i.e., SEQ.ID.NOS: 15, 16, 23 and 24).

Information Disclosure Statement

3. The Information Disclosure Statements (IDS) filed on 5/23/08 is acknowledged and a signed copy of the same is attached to this office action.

Claim Rejections moot

4. In view of cancelation of claims 1-82 , all the rejections of record are moot.

New Claim Rejections under 35 U.S.C. 112 based on new claims

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 83-86, 91-92, 97-111, 116-117 and 122-132 are rejected under 35 U.5.C. 112, first paragraph , as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The claims 83-86, 91-92, 97-107 are drawn to pharmaceutical composition comprising an amino acid sequence at least 95% identical to amino acids 29-533 of SEQ ID NO: 2, wherein said composition, when administered to female mice, eliminates or reduces the level of *C. trachomatis* in the lower genital tract following intra vaginal challenge. Claims 108-111, 116-117 and 122-132 are drawn to pharmaceutical composition comprising an amino acid sequence at least 95% identical to amino acids 29-533 of SEQ ID NO: 2, wherein said composition, wherein said polypeptide when administered to a subject induces a cellular immune response or a humoral immune response that recognizes the polypeptide of SEQ.ID. NO:2. Enablement of a "pharmaceutical composition" is considered to rest on a teaching of in vivo administration for purposes consistent with the intended use disclosed in the specification. The disclosed intended use for the claimed pharmaceutical compositions is for the elimination or reduction of *C. trachomatis* in the lower genital tract of human infections Thus, the nature of the invention is a therapeutic composition used in the treatment of sexually transmitted venereal diseases.

Although the specification discloses the claimed composition, and general methods for formulating compositions in pharmaceutically acceptable carriers, there is insufficient guidance which would enable one skilled in the art to use the claimed compositions for their intended purpose, viz., for the generation of a protective immune response against human Chlamydial infections

At the time the invention was made, pharmaceutical compositions comprising the claimed compositions were not routinely used for eliminating human cervical infections caused by various *C.trachomatis* serotypes and pelvic inflammatory diseases it appears to be complex task (see Brunham et al 2005, Nature Reviews, vol 5, pages 149-161, see pages 150 and 158). The specification lacks guidance by way of general methods or working examples which teach an "effective amount" of antibody or cellular response which would be used for this purpose.

Lack of working examples is given added weight in cases involving an unpredictable and undeveloped art. It is unpredictable whether the claimed pharmaceutical composition, which is disclosed as being immunogenic, would have the added property of generating an immune response sufficient to eliminate *C.trachomatis* and treat disease caused by *C.trachomatis* , because the specification has not disclosed a link or nexus between the generation protective antibody or T-cell mediated immune response that eliminates Chlamydial infections or disease (see pages 152-156) . Further, it is not routine in the art of *C.trachomatis* to use compositions analogous to the claimed compositions for this purpose. Accordingly, there is no objective basis upon which the skilled artisan would reasonably be able to determine or predict an amount of the claimed composition/vaccine effective for its intended use. Therefore, undue experimentation would be required to make and use the invention.

Conclusion

7. No claims are allowed.

This application contains claims 87-90, 93-96, 112-115, 118-121 drawn to an invention nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m except First Friday of each bi-week. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon can be reached on (571) 272-0898.

/ Padma Baskar /
Examiner 1645

/Shanon A. Foley/

Supervisory Patent Examiner, Art Unit 1645